

## **REMARKS**

Claims 1-40 are now pending in the application. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **REJECTION UNDER 35 U.S.C. § 102**

Claims 1-40 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Holcomb (U.S. Pat. No. 6,042,531). This rejection is respectfully traversed.

At the outset the Applicant submits that Holcomb is not analogous to the methods for controlling an element of a medical device within a body, as in the presently amended claims. Furthermore, Holcomb does not anticipate the methods for controlling an element of a medical device within a body as in the presently amended claims.

### **HOLCOMB Is Not Analogous Art**

HOLCOMB discloses the application of the particular magnetic field that is not analogous to the methods of the present claims, because Holcomb uses a plurality of electromagnets oriented to define four vertices of a quadrilateral shape (two positive poles defining opposite diagonal vertices and two negative poles defining opposite diagonal vertices), which is used for therapeutic electromagnetic treatment of tissues and not for controlling a medical device within a body. HOLCOMB is non-analogous for at least two reasons:

- 1) HOLCOMB teaches the application of a three-dimensional, magnetic, steep gradient field for the purpose of therapeutic application to the human body tissues (Col. 8, ll. 15-19), where the field gradients “blocks varying degrees of sodium and calcium function”; such a purpose is not analogous to the application of controlling an element of a medical device within a body
- 2) HOLCOMB does not give any indication of whether the generated fields having steep slopes in the field gradient (Fig. 7) are intended for, or are capable of controlling an element of a medical device within a patient’s body; as such, the HOLCOMB fields having steep slopes cannot be considered as being relevant to the problem of controlling a device in a patient’s body, if such fields are not inherently capable of controlling a device with a body.

For the above reasons, the Applicant submits that the rejection of the present claims based on HOLCOMB is inappropriate, since HOLCOMB is not analogous art.

#### HOLCOMB Is Not Anticipatory

Even if HOLCOMB could be considered to be analogous, it still does not anticipate the presently claimed methods, because HOLCOMB is not enabling as to the application of at least two different magnetic fields for controlling an element of a medical device within a body. The Federal Circuit has repeatedly held that for a reference to anticipate the claimed invention, it must enable a person of ordinary skill in the art to produce the claimed invention. *In re Paulsen*, 30 F.3d 1475, (Fed. Cir. 1994). The Applicant submits that HOLCOMB is not enabling for at least two reasons:

- 1) HOLCOMB teaches the application of a three-dimensional, magnetic, steep gradient field, which particular field may have only a possibility, at best, of controlling a medical device within a body, and cannot be considered as inherently being capable of controlling an element of a medical device within a body that is responsive to a magnetic field;
- 2) HOLCOMB provides (in Table I) evidentiary data in support of a biological effect that is dependent upon the field intensity; the magnetic field generated by generator # 1 + generator #2 results in the generation of only +81.4 to -80 Millitesla at a distance of only 2.9 inches, and the generation of only +78 to -75 Millitesla at a distance of only 4.2 inches. (HOLCOLM, col. 28, ll. 55-67). This field strength is not nearly the same as the field strength disclosed in the present application (.15 Tesla at a distance of 6 inches from the magnet, paragraph 44 of the present application as published in 20020100486), which the Applicant submits is necessary for controlling an element of a medical device within a patient's body. Moreover, HOLCOMB's invention generates a magnetic field having a complexity of field directions (shown in Fig. 7), which is very different from the parallel magnetic field lines of the present application (Fig. 14), which tend to align a medical device in a direction parallel to the magnet's axis. (see paragraph 65 of the present application as published in 20020100486). Therefore, the HOLCOMB invention also does not generate a magnetic field having uniform direction lines suitable for controlling a magnetic medical device.

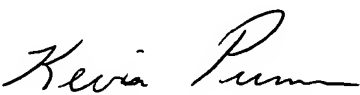
Thus, the HOLCOMB reference cannot be considered to enable a person of ordinary skill in the art to produce the claimed invention of controlling an element of a medical device within a body. As such, HOLCOMB cannot anticipate the methods of the presently amended claims, which the Applicant submits are allowable for at least these reasons.

### CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 726-7500.

Respectfully submitted,

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